Supreme Court, U.S.
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No. ____ OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) mandates pre-emption of all state law causes of action for injuries caused by medical devices which have received pre-market approval from the Food and Drug Administration?

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PETITION FOR A WRIT OF CERTIORARI

Deborah Eddy and Thomas Eddy respectfully petition for a writ of certiorari to review the judgment of the Superior Court of Pennsylvania in this case.

OPINIONS BELOW

The Opinions of the Superior Court of Pennsylvania (App. 1-7) and the Court of Common Pleas of Allegheny County (App. 8-12) are unreported.

JURISDICTION

The judgment of the Superior Court of Pennsylvania was entered on December 5, 1995. The Supreme Court of Pennsylvania denied a timely Petition for Allowance of Appeal on March 31, 1997. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257(a).

STATUTE INVOLVED

21 U.S.C. § 360k(a) provides that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT OF THE CASE

Petitioner Deborah Eddy sustained serious injuries to her right eye from an infection, acanthamoeba keratitis, as a result of disinfecting her gas permeable contact lenses in accordance with faulty instructions which accompanied her contact lens cleaning system.[1] The lens cleaner and conditioning solution which comprised the cleaning system constituted "Class III medical devices" which had received pre-market approval from the Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments[2] (the "MDA") to the Federal Food, Drug and Cosmetic Act.[3]

Mrs. Eddy and her husband, Petitioner Thomas Eddy, brought suit in the Court of Common Pleas of Allegheny County, Pennsylvania against Respondents, the manufacturer and sellers of the cleaning system,[4] asserting claims for negligence, strict liability and breach of warranty.

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[1] The written instructions provided with the cleaning system call for rinsing the contact lenses with tap water, a procedure which, Petitioners have alleged, foreseeably resulted in Mrs. Eddy's eye infection.

[2] 21 U.S.C. §§ 360c-3601 (1988).

[3] 21 U.S.C. §§ 301-395 (1988).

[4] The cleaning system, consisting of "Boston Advance Cleaner" and "Boston Advance Conditioning Solution", was manufactured and distributed by Respondent Polymer

The Court of Common Pleas, per McFalls, J., granted summary judgment in favor of Respondents,[5] holding that all of Petitioners' claims are pre-empted by the MDA. The court reasoned that

> The product involved in the instant action carries a Class III classification under federal regulations. As such, the lens cleaner and solution require pre-market approval by the FDA. Because pre-market approval is required, the MDA preempts state tort law claims. (App. 12)

The Pennsylvania Superior Court, per Rowley, P.J., Tamilia, J. and Hester, J., affirmed,[6] deeming itself bound by the earlier decision of a panel of that court in *Green v. Dolsky*.[7] (App. 4-5) The Pennsylvania Supreme Court, having affirmed the Superior Court's decision in *Green* in the interim, denied Petitioners' request for discretionary review.[8]

Technology Corporation, a wholly-owned subsidiary of Bausch & Lomb, Inc. A kit containing Boston Advance cleaner and solution was included with the contact lenses which Mrs. Eddy purchased from Respondent Dr. James H. Letham, O.D., and Mrs. Eddy purchased additional bottles of Boston Advance cleaner and solution from Respondent Thrift Drug, Inc.

[5] The October 20, 1994 Opinion of the Court of Common Pleas is set forth at App. 8-12.

[6] The December 5, 1995 Opinion of the Superior Court is set forth at App. 1-7.

[7] 641 A.2d 600 (Pa. Super. 1994), *aff'd*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997).

[8] The March 30, 1997 Order of the Pennsylvania Supreme Court is set forth at App. 13.

REASONS FOR ALLOWANCE OF THE WRIT

In *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), this Court held that the MDA does not pre-empt most state tort law claims for injuries caused by medical devices excused from pre-market approval under the MDA due to "substantial equivalence" with pre-existing devices. Appellate courts in several jurisdictions have since held that the reasoning of *Medtronic* indicates that common law claims for injuries from devices which have received pre-market approval are also not pre-empted by the MDA. However, the Pennsylvania courts hold that pre-market approval automatically results in pre-emption of state law claims.

I. The Pennsylvania Courts' Interpretation of the MDA Preemption Provision is in Conflict With the Decisions of Other Jurisdictions.

The decisions of the Pennsylvania courts in this case and in *Green, supra* n.7, squarely conflict with the decisions of courts of last resort[9] in at least three states which have held that pre-market approval does not mandate pre-emption of common law claims. *See Kernats v. Smith Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. Ct. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *petition for cert. filed* (Mar. 4, 1997) (No. 96-1405);[10] *Fiore v. Collagen*

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[9] These cases are deemed to be decided by "courts of last resort" because the highest courts of the states involved have denied discretionary review.

[10] This Court has invited the Solicitor General to file a brief in the *Kernats* case expressing the views of the United States. *See*

Corp., 930 P.2d 477 (Ariz. Ct. App. 1996), *review denied*, No. CV-96-044-PR (Jan. 14, 1997), *petition for cert. filed* (Apr. 10, 1997);[11] *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996), *review denied*, 1997 Cal. LEXIS 833 (Feb. 19, 1997).[12] In addition, intermediate appellate courts of several other states have held that claims relating to devices which have received pre-market approval are not pre-empted. *See Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16 (App. Div. 1997); *Hernandez v. Coopervision, Inc.*, 691 So. 2d 639 (Fla. Dist. Ct. App. 1997); *Walker v. Johnson & Johnson Vision Products, Inc.*, 552 N.W.2d 679 (Mich. App. 1996).[13]

The decision in this case is also contrary to the decision of the Ninth Circuit in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996). Although *Kennedy* was decided before *Medtronic*, the Ninth Circuit subsequently held that its "prior decisions narrowly construing the MDA's preemption clause", including *Kennedy*, "are consistent with

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Kernats v. Smith Industries Medical Systems, Inc., 137 L. Ed. 2d 817 (May 12, 1997).

[11] *Fiore* was decided by the Arizona Court of Appeals one day before this Court's decision in *Medtronic*; all other cases cited in this paragraph were decided after *Medtronic*.

[12] *But cf. Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997) (criticizing *Armstrong*). Because the Supreme Court of California has not denied discretionary review in *Steele*, it is not a decision of a court of last resort.

[13] *Sowell*, *Hernandez* and *Walker* each involved contact lenses, whose safety characteristics, and resulting pre-market approval process and labeling requirements, overlap those of lens cleaners and conditioning solutions.

Medtronic". *Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807, 812 (9th Cir. 1996), *cert. denied*, 117 S. Ct. 754 (1997).[14]

The Pennsylvania courts' interpretation of the MDA is at odds with various other courts' interpretations of the same federal statute. Certiorari is therefore appropriate to restore the uniform application of federal law.

II. The Pennsylvania Courts' Interpretation of the MDA Preemption Provision is in Conflict With the Reasoning of This Court's Medtronic Decision.

Although *Medtronic* did not involve a device which had received pre-market approval, it established a framework for analysis of 21 U.S.C. § 360k(a) which is generally applicable to all MDA pre-emption claims. Two features of the majority's analysis are particularly pertinent here:

First, the Court held that the MDA pre-emption provision is ambiguous, and that the FDA's interpretation is therefore to be accorded substantial weight. *See*

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[14] *But cf. Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) ("to the extent we concluded in *Kennedy* that the MDA cannot preempt *any* state common-law causes of action, the conclusion cannot survive in light of the concurring and dissenting opinions in *Medtronic*") (emphasis in original). *Papike* concerned a Class II device which was subject to a specific, affirmative labeling regulation. *See id.* at 739. It did not repudiate *Kennedy*'s holding that pre-market approval of Class III devices does not require pre-emption of common law claims.

Medtronic, 116 S. Ct. at 2255-56 (Stevens, J., for the Court)[15] ("[T]he FDA . . . is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted. . . . The ambiguity in the statute – and the congressional grant of authority to the agency on the matter contained within it – provide a 'sound basis' . . . for giving substantial weight to the agency's view of the statute.") (citations omitted).[16]

The FDA has consistently taken the position that the MDA does not pre-empt tort claims based on generally applicable duties. Thus, the FDA has promulgated regulations which "note that the statute is not intended to pre-empt 'State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices. . . . ' " *Id.* at 2257, quoting 21 CFR § 808.1(d)(1) (1995).

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[15] Justices Kennedy, Souter and Ginsburg concurred in Justice Stevens's opinion in its entirety. Justice Breyer concurred in Parts I-III, V and VII of Justice Stevens's opinion. The passages cited here are drawn from Part V, in which a majority of the Court concurred.

[16] *See also* 116 S. Ct. at 2260-61 (Breyer, J., concurring) ("[T]he MDA's pre-emption provision is highly ambiguous. . . . [C]ourts may infer that the relevant administrative agency possesses a degree of leeway to determine which . . . administrative actions will have pre-emptive effect. . . . At least in present circumstances, no law forces the FDA to make its requirements pre-emptive if it does not think it appropriate.").

In contrast to this Court's careful consideration of the FDA's position, the Pennsylvania courts have accorded that position virtually no weight. The opinions in this case do not mention the FDA's interpretation; the prior decision on which the Superior Court relies in this case mentions the FDA's position only to reject it. *See Green*, 641 A.2d at 606 ("[W]e view the FDA opinion letter as merely advisory and not dispositive.").

Second, in keeping with the FDA's interpretation, this Court held in *Medtronic* that common law labeling or warning requirements are not pre-empted under the MDA:

> [T]he general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. . . . [T]he predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. . . . These state requirements therefore escape pre-emption, . . . because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices. . . . As a result, none of the Lohrs' claims based on allegedly defective . . . labeling are pre-empted by the MDA.

116 S. Ct. at 2258 (Stevens, J., for the Court).

Although pre-market approval is more rigorous than the substantial equivalence review at issue in *Medtronic*, differences in the FDA procedures affect only the nature

of the federal requirements, and have no bearing on whether the state requirements are "with respect to" the device in question. The "generality" or "general applicability" of a state law requirement such as the duty to warn of known latent dangers is not affected by the specificity of any federal requirement. Consequently, under the reasoning of *Medtronic* and the FDA regulations embraced therein, general state law tort claims are not pre-empted.

By focusing solely on the nature of the federal requirements and disregarding the generality of the state requirements, the Pennsylvania courts have adopted an interpretation of the MDA which is contrary to the reasoning of this Court. Certiorari is appropriate to correct the Pennsylvania courts' continuing error.

III. Whether Pre-Market Approval Insulates Manufacturers of Medical Devices from Tort Liability is an Important Issue.

A holding that state law claims are pre-empted by virtue of a product's pre-market approval has the "effect of granting complete immunity from design defect liability" for that product, and thus "remov[ing] all means of judicial recourse for those injured" thereby. *See Medtronic*, 116 S. Ct. at 2251 (Stevens, J., plurality opinion). The broad immunity accorded by the Pennsylvania courts' interpretation would undermine the important role of state tort law in encouraging product safety and distributing losses among product users. *See generally Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) ("[P]ublic policy demands

that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.").

Although most new Class III medical devices presently avoid pre-market approval by means of the substantial equivalence process, manufacturers will more readily undergo the pre-market approval process if it is held to insulate them from liability for injuries caused by their products. Moreover, the already substantial number of court cases involving pre-market approval will certainly grow as new devices are developed which are not equivalent to pre-existing devices. Resolution of the preemption issue may therefore control the outcome of numerous cases affecting many people and products.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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DEBORAH EDDY AND THOMAS EDDY, Appellants v. POLYMER TECHNOLOGY CORP., THRIFT DRUG, INC., AND DR. JAMES LETHAM, O.D.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA NO. 1941 PITTSBURGH 1994

Appeal from the Order Entered October 20, 1994, Docketed October 21, 1994, in the Court of Common Pleas of Allegheny County, Civil Division, No. GD 92-16038.

DEBORAH EDDY AND THOMAS EDDY, Appellants v. POLYMER TECHNOLOGY CORP., THRIFT DRUG, INC., AND DR. JAMES LETHAM, O.D.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA NO. 1942 PITTSBURGH 1994

Appeal from the Order Entered October 20, 1994, in the Court of Common Pleas of Allegheny County, civil Division, No. GD 92-16038.

BEFORE: ROWLEY, P.J., and TAMILIA and HESTER, JJ.

MEMORANDUM: Filed: December 5, 1995

We are asked in this appeal to decide if the trial court properly granted summary judgment to appellees after concluding that appellants' claims were preempted by the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA). After careful review of the trial court's reasoning and the arguments raised by both parties herein, we affirm.

Appellant Deborah Eddy filed a claim against appellees Polymer Technology Corporation (Polymer), Thrift Drug, Inc. (Thrift), and Dr. James H. Letham, O.D. (Dr. Letham) after contracting an eye infection allegedly caused by inadequate instructions regarding the proper method of disinfecting her gas permeable contact lenses. She sought damages from both the corporate defendants and Dr. Letham individually under theories of negligence, strict liability, breach of implied warranty, and, on behalf of Thomas Eddy, a loss of consortium. Relying on this Court's decision in *Green v. Dolsky*, 433 Pa.Super. 556, 641 A.2d 600 (1994), *appeal granted*, 539 Pa. 678, 652 A.2d 1324 (1994), the trial court granted appellees' motions[1] for

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[1] The trial court issued two orders, both filed on October 20, 1994. The first granted summary judgment in favor of appellees Polymer and Thrift. The second granted summary judgment in favor of appellee Dr. Letham. Appellants' appeals of both orders were consolidated on December 21, 1994.

summary judgment[2] on the basis that appellants' claims were preempted by federal law, specifically that portion of the MDA which controls regulation of Class III medical devices. 21 U.S.C. § 360k.

Any discussion regarding whether a cause of action under common law is preempted by federal statute begins with a strong presumption against preemption. *Mazaike v. Bank One, Columbus, N.A.*, 439 Pa.Super. 95, 653 A.2d 640 (1994), *appeal granted*, ___ Pa. ___, 659 A.2d 557 (1995). However, preemption will be found where: 1) Congress' intent to preempt a field is expressly stated; 2) state law is preempted by virtue of a conflict with federal law; or 3) the federal law at issue so thoroughly occupies a field as to leave no doubt with respect to Congress' intent that state law may not supplement federal law on the subject. *Green, supra.* State regulation to which preemption applies is not limited to express regulatory actions taken by a state, but "can be effectively exerted through an award of damages[,]" which may have the result "of governing conduct and controlling policy." *Cipollone v. Liggett Group, Inc.*, 504 U.S. ___, ___, 112 S.Ct. 2608, 2620, 120 L.Ed.2d 407 (1992), *quoting San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247, 79 S.Ct. 773, 780, 3 L.Ed.2d 775 (1959).

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[2] Summary judgment is proper, under Rule 1035, when a review of the pleadings, depositions, answers to interrogatories, admissions on file and supporting affidavits demonstrate that there is no genuine issue of material fact, and the movant is entitled to summary judgment as a matter of law. Pa.R.C.P. 1035(a); *Marks v. Tasman*, 527 Pa. 132, 589 A.2d 205 (1991).

The facts presented by this case are essentially identical to those presented in *Green, supra.* In *Green* this Court was confronted with claims for damages resulting from collagen treatments. The plaintiff asserted the same causes of action as have been asserted by appellants in this case, all of which, as here, were presented within the context of the identical provision of the MDA.[3] *Id.* at 558, 641 A.2d at 602. As was the case in *Green,* there is no dispute in this case that the products involved are classified as Class III medical devices. As such, they are subject to the most stringent oversight authorized by regulations promulgated under the FDCA. *King v. Collagen Corp.,* 983 F.2d 1130 (1st Cir. 1993). In affirming the trial court's grant of summary judgment in favor of defendant Collagen Corporation in *Green,* this Court determined that "a finding in favor of [appellants] on any of their alleged state tort law claims would impose additional or different

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[3] Title 21 U.S.C. § 360k provides:

§ 360k State and Local Requirements Respecting Devices.

(a) General Rule

Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement.

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

requirements on [appellee] . . . whose product . . . has already received FDA approval. Such requirements are in conflict with the MDA and thus, the [appellants'] state law claims are therefore preempted." *Id.* at 567, 641 A.2d at 605. Contrary to appellants' assertions, we are bound by prior decisions of this Court. *Lower Paxton Township v. U.S. Fid. & Guar. Co.*, 383 Pa.Super. 558, 573, 557 A.2d 393, 400 (1989). Therefore, we conclude, as did the trial court, that summary judgment in favor of Polymer and Thrift, on the basis that federal law preempted appellants' state tort law claims, was proper.

There is a distinction between this case and *Green*, however, which requires discussion. In *Green*, "[t]he sole issue on appeal [was] whether the trial court erred in granting summary judgment in favor of [the manufacturer] Collagen[.]" *Green*, 433 Pa.Super. at 559, 641 A.2d at 602. Here, appellants claim the trial court erred in granting summary judgment in favor of Dr. Letham, as well as the corporate defendants, Polymer and Thrift.[4]

Appellants' complaint alleged three causes of action against Dr. Letham: negligence, breach of implied warranty, and strict liability. However, we note from the

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[4] Subsequent to this Court's decision in *Green*, the Court of Appeals for the Third Circuit had occasion to address the issue of federal preemption of state law causes of action in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994), *cert. denied*, ___ U.S. ___, 115 S.Ct. 429, ___ L.Ed.2d ___ (1994). The Court of Appeals concluded that while the appellant's state tort law remedies against the manufacturer of an intraocular lens implant device were "displaced" by the provisions of the MDA, she was free to assert a right of redress in state court against her physician. *Id.* at 546.

record that appellants' response to appellees' motions for summary judgment, as well as the accompanying brief, are entirely devoted to an argument generally addressing the issue of whether state law causes of action are pre-empted by federal law. There is not a single reference to the causes of action brought individually against Dr. Letham. Similarly, the trial court's opinion does not distinguish the reasons it granted summary judgment to Polymer and Thrift from those it relied upon in granting summary judgment to Dr. Letham. Furthermore, appellants' appellate brief fails to provide a single argument that draws a distinction between the alleged impropriety of the trial court's grant of summary judgment in favor of Polymer and Thrift, as opposed to that granted Dr. Letham. The only argument appellants advance with respect to Dr. Letham appears in appellants' reply brief and is directed solely to a claim that Pennsylvania case law does not preclude a strict liability claim against Dr. Letham. That issue was specifically addressed by this Court in *Cafazzo v. Central Medical Health Services, Inc.*, 430 Pa.Super. 480, 635 A.2d 151 (1993), *appeal granted*, 538 Pa. 608, 645 A.2d 1311 (1994), and was found to be without merit.[5]

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[5] Appellant's reply brief relies on the fact that the Supreme Court granted allocatur in *Cafazzo*. Appellants apparently equate the grant of allocatur with a reversal. We decline to presume how the Supreme Court will rule, or when, and say again that we are bound by prior decisions of this Court. This Court's decision in *Cafazzo* is dispositive of appellants' claim that a strict product liability action against Dr. Letham is not precluded under Pennsylvania case law. It is, *Cafazzo*, 430 Pa.Super. at 488, 635 A.2d at 155 (a physician is not a "seller" under 402A, Restatement of Torts, and therefore is not subject to

Viewing all the evidence in a light most favorable to appellants, we cannot agree that the trial court committed an error of law or abused its discretion in granting summary judgment in favor of appellees Polymer and Thrift on the grounds of federal preemption. *Green, supra.* Dr. Letham is not subject to a claim for damages under a theory of strict product liability. *Cafazzo, supra.* Furthermore, appellants have waived any claims that the trial court erred in granting summary judgment in favor of Dr. Letham on the negligence and breach of implied warranty causes of action for failure to argue them in their brief. Pa.R.A.P. 2119; *Harvilla v. Delcamp,* 521 Pa. 21, 555 A.2d 763 (1989), *citing Commonwealth v. Jackson,* 494 Pa. 457, 431 A.2d 944 (1981).[6] Accordingly, we affirm the orders entered on October 20, 1994.

Orders affirmed.

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a claim for strict product liability); *see also Bigansky v. Thomas Jefferson University Hosp.,* ___ Pa.Super. ___, 658 A.2d 423 (1995).

[6] We are not unaware that a recent decision of this Court affirmed a trial court's denial of preliminary objections, on the grounds that common law liability was not preempted by the provisions of the National Traffic and Motor Vehicle Safety Act (the Safety Act), 15 U.S.C. § 1381 *et seq. Heiple v. C.R. Motors Inc., and G.M. Corp.,* ___ Pa.Super. ___, ___ A.2d ___ (1995) (No. 808 Pittsburgh 1994, filed 7/31/95). The panel concluded that the savings clause included in the Safety Act expressly "does not exempt a person from liability at common law," 49 U.S.C. § 30103(e), and thus, common law causes of action were preserved. We distinguish *Heiple* on the basis that a different federal statute was at issue: "[t]he MDA [unlike the Safety Act] does not contain a savings clause expressly precluding exemption from liability under state common law." *Heiple,* ___ Pa.Super. at ___, ___ A.2d ___ at 34.

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
CIVIL ACTION - LAW

DEBORAH EDDY and THOMAS EDDY,

Plaintiffs,

vs.

POLYMER TECHNOLOGY CORPORATION; THRIFT DRUG, INC. and JAMES H. LETHAM, O.D.,

Defendants.

No. G.D. 92-16038

OPINION

Plaintiffs filed suit against defendants for injuries sustained from an infection contracted by wife-plaintiff and allegedly caused by the wife-plaintiff's disinfection of gas permeable contact lenses. The action is based on counts of negligence, strict liability, breach of warranty and loss of consortium.

In the complaint, plaintiffs allege that wife-plaintiff, a patient of Dr. Letham, purchased from him a gas permeable contact lens manufactured and distributed by Polymer. A user kit was included with the lens. The kit contained a bottle of Advance Conditioning Solution and Advance Cleaner supplied by Polymer bearing the "Boston" trademark. (Polymer is a wholly owned subsidiary of Bausch & Lomb, Inc.).

Wife-plaintiff then at the same time, purchased a bottle of contact lens cleaner and contact lens conditioning solution from Thrift Drug and manufactured and distributed by Polymer.

After using the cleaner and conditioning solution, wife-plaintiff developed an eye infection diagnosed as Acanthamoeba Keratitis. The infection was allegedly caused from rinsing the lens with tap water after cleaning. According to the complaint, wife-plaintiff cared for her lens in accordance with the instructions given to her by Dr. Letham and those which were distributed along with the cleaner and conditioning solution by Polymer and sold by Dr. Letham and Thrift Drug.

Defendants filed Motions for Summary Judgment which were granted by orders of court of the Honorable Patrick McFalls on October 20, 1994.

Defendants moved for Summary Judgment based on the argument that plaintiffs' state tort law claims are preempted by federal law.

Pa. R.C.P. 1035 states in relevant part:

> (a) After the pleadings are closed . . . any party may move for summary judgment on the pleadings and any depositions, answers to interrogatories, admissions on file and supporting affidavits.
>
> (b) The judgment sought shall be rendered if the pleadings, depositions, answer to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. . . .

In considering a Motion for Summary Judgment, the court must view the record in the light most favorable to the non-movant. Only where the pleadings, answers to interrogatories, depositions, admissions and affidavits establish that the movant's right to relief is clear and free from doubt should a court grant a summary judgment. *McNeal v. City of Eastron,* 143 Commw. Ct. 151, 598 A.2d 638, 639 (1991). When a Motion for Summary Judgment is made and supported by evidence of record, the non-movant may not rest on his allegations but rather must set forth specific facts of record showing there is a genuine issue for trial. *McNeal* at 639, 640.

In the instant action, summary judgment was properly granted in favor of defendants because federal law pre-empts the plaintiffs' state tort law claims.

21 U.S.C. § 360K provides:

§ 360K State and Local Requirements Respecting Devices

(a) General Rule

Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –

(1) Which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) Which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Recent decisions from the Superior Court and the United States District Court address the issue present in the case at hand. In the case of *Green v. Dolsky*, 433 Pa. Super. 556, 641 A.2d 600 (1994), the issue before the court was whether the trial court erred in granting Summary Judgment in favor of Collagen on the basis that the MDA preempted the Greens' state tort law claims. The Superior Court considered cases from other jurisdictions, including federal cases, to determine the issue before it. In its opinion the Court stated:

> Generally, pre-emption may be express or implied, and it is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose . . . when Congress is silent on the matter, state law will be preempted by federal law "when (a) compliance with both state and federal law is impossible or, (b) when state law stands as an impediment to a federal purpose". *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 747 (M.D. Pa. 1992).

Moreover, the United States District Court in the case of *Gerber, et al. v. Medtronic Inc.*, 142 P.L.J. 396 (1994), when considering a motion for summary judgment in a case involving a Class III product and § 360K (a) stated:

> State requirements relating to the safety and effectiveness of medical devices regulated pursuant to the MDA may include common law tort standards of liability, as well as legislation and administrative regulations. . . . Following the weight of authority, I hold that because plaintiffs' strict liability, negligence, failure to warn and breach of warranties claims with respect to the model No. 4003 lead would impose safety

and effectiveness requirements in addition to the FDCA, they are all preempted by the MDA.

The product involved in the instant action carries a Class III classification under federal regulations. As such, the lens cleaner and solution require pre-market approval by the FDA. Because pre-market approval is required, the MDA preempts state tort law claims.

In the case at hand and in light of federal statutes and regulations and applicable case law, summary judgment was properly granted in favor of the defendants because plaintiffs' state tort law claims are preempted by the MDA.

BY THE COURT,

/s/ McFalls, J.

cc: Harlan S. Stone, Esq.
Robert J. Behling, Esq.
Kerry A. Kearney, Esq.
Joel Persky, Esq.

IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

DEBORAH EDDY AND THOMAS EDDY, Petitioners. v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC., AND DR. JAMES H. LETHAM, O.D., Respondents.	:	Nos. 004 and 005 Western District Allocatur Docket 1996 Petition for Allowance of Appeal from Superior Court

ORDER

PER CURIAM:

AND NOW, this 31st day of March, 1997, the Petition for Allowance of Appeal is hereby DENIED.